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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,063	DAVENPORT ET AL.	
	Examiner	Art Unit	
	ERNST ARNOLD	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *25,27-38,40-48,50,52 and 53* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25, 27-38, 40-48, 50, 52 and 53* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24, 26, 39, 49 and 51 have been cancelled. Claims 25, 27-38, 40-48, 50, 52 and 53 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 6/30/11 are acknowledged and have been fully considered. Claims 25, 27-29, 32-34, 36, 38, 43 and 50 were rejected under 35 U.S.C. 102(b) as being anticipated by The American journal of obstetrics and diseases of women and children 1912, volume 66, W. Wood & Co., pp 893-894 as evidenced by Barth et al. (Nahrung 1997, 41(1): 2-12 Abstract only). Applicant has amended the claim to overcome the rejection and it is withdrawn.

Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 27-38, 40-48, 50, 52 and 53 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Lon (Feeding and Care of the Horse second edition; 1996, Lipponcott Williams and Wilkins, Media, Pa) and Lewis, Lon (Equine Clinical Nutrition Feeding and Care; 1995, Williams & Wilkins, Media, Pa) and Parsons, HS., (Care and Management of the Older Horse; 2001, Trafalgar Square Publishing, North Pomfret, Vermont) and Weese et al. (Abstract; J. Am Vet. Med. Assoc 1999, 214(2), 229-32).

Applicant claims:

25. (currently amended) A method for reducing energy deficit in a mammal with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract disease, comprising the step of entencally administering to the mammal an energy promoting effective amount of a composition having between about 2% to about 2.5% ~~less than 3%~~ fat by weight comprising an effective proportion of components;

wherein the composition comprises a protein component comprising whey powder.

Determination of the scope and content of the prior art

(MPEP 2141.01)

In the feeding and care of the horse, Lewis provides chapters on Energy (chapter 1), Minerals (chapter 2), Vitamins (chapter 3), Harvested Feeds (chapter 4), Diet evaluation (Chapter 6), Horse Feeding Practice (chapter 8) and Feeding and Care of Horses with Health Problems (chapter 17) (page 4 of 14). Lewis teaches whey, which is what remains after milk proteins have been removed following drying, still contains 17-18% protein *but is primarily lactose* and is a source of protein for horses (page 88). It is the Examiner's position that dried **whey is a powder** in the absence of evidence to the contrary. Lewis teaches that horses over 3 years of age have little lactase which can be a problem for older horses who consume enough lactose to cause diarrhea (page 88). Lewis teaches that common horse feed contain 2-6% fat (page 18, right column). *Thus feed supplements of 2% fat are known*. Lewis teaches feeding and care of horses with health problems including **diarrhea** (a digestive tract condition) liver disease (hepatic dysfunction) and kidney failure (renal dysfunction) (chapter 17 title page). ***Thus, all of the instant disorders are covered in Lewis***. Horses with **liver disease**, which reads on hepatic dysfunction, should be **tube fed**, hence enterally, with a diet that **meets energy needs**, **protein needs**, and be low in or *not contain fat* (page 296, left column). Lewis teaches that in **renal failure** a vitamin supplement is recommended to be added to the diet (page 296 Kidney Failure). Harvested feeds for horses include oats, **hay**, brewer's yeast, dried milk products, probiotics and bioflavonoids (chapter 4 title page). Vitamins include vitamins, A B1, B2, C, D, E, K, niacin, pantothenic acid, pyridoxine, biotin, floccain, cobalamin, and choline (chapter 3, title page). The composition has an effective proportion of components in the absence of evidence to the contrary. (Please note that the Examiner only had a limited preview of this book on Google books and could not access all the pages at this time.)

In equine clinical nutrition, Lewis (*the same author of the feeding and care of the horse above*) teaches that *alfalfa* is hay (page 16, right column). Lewis teaches that proteins are composed of **22 different amino acids** and feeds provide a sufficient amount of *each amino acid* (page 16, left column). Lewis teaches **minerals** for horses including sodium chloride salt, calcium, molybdenum, potassium, iron, copper, iodine, selenium, manganese and magnesium (chapter 2 title page). Vitamins are also taught (chapter 3, title page) as well as harvested feeds for horses (chapter 4, title page). Sick horse feeding and nutritional support is taught which includes a section on **tube feeding** horses, horses with *intestinal disorders, renal failure and hepatic dysfunction* (chapter 17, title page). The horse with diarrhea can be feed by stomach tube (page 408, diarrhea). Microorganisms from yogurt or commercial inoculants can be administered (page 408, right column). Vitamin supplement for *renal failure* is recommended (page 413, left column). The composition has an effective proportion of components in the absence of evidence to the contrary.

Parsons teaches care and management of the older horse and adding a variety of supplements to the diet of the horse such as nutraceuticals such as *chondroitin sulfate and glucosamine(*which renders obvious other glucosamine derivatives) (title page, 88 and 89). Parsons teaches carbohydrates such as glucose and galactose as **monosaccharides** as energy supplying nutrients (Figure 1-3, page 10 of 10). Parsons teaches adding *probiotics* to horses with diahrrea and to *avoid extra fat* if the diarrhea is associated with liver disease (pages 210 and 211). Electrolytes can be administered by **stomach tube** (page 211). In liver disease, the vet may insist on **tube feeding** (page 235). A good quality vitamin supplement is recommended and fats and oils are to be kept to a minimum (page 237). In fact, Parsons teaches not to supplement

your horse's normal feed with additional fat or oil but to **maintain adequate protein levels** and high in carbohydrates (page 236 to top of page 237). Carbohydrates include glucose and galactose monosaccharides as discussed above. The composition has an effective proportion of components in the absence of evidence to the contrary. Micronized materials are taught (page 237).

Weese et al. teach oral administration of lactase to a lactose intolerant foal (Abstract; J. Am Vet. Med. Assoc 1999, 214(2), 229-32). Thus, the concept of administration of lactase to lactose intolerant equines is established in the art.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Lewis is that Lewis do not expressly teach adding between about 1 to 5 wt% lactase or that the whey powder is smaller than about 45 mesh to a composition that is liquid or powder form in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition. This deficiency in Lewis is cured by common sense and the teachings of Weese et al.

2. The difference between the instant application and Lewis is that Lewis do not expressly teach adding the nutrient component, feed component, amino acid chelate, trace mineral, monosaccharides, amino acids, and functional food component as instantly claimed to a human, dog, cow, pig, goat or sheep in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition. This

deficiency in Lewis is cured by common sense and the teachings Parsons and Lewis (Equine Clinical Nutrition).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add between about 1 to 5 wt% lactase, as suggested by common sense and Weese et al., to the composition of Lewis in liquid or powder form, or that the whey powder is smaller than about 45 mesh in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the textbook of Lewis clearly teaches that older horses lack lactase and a whey protein supplement rich in lactose can cause diarrhea. The artisan would add lactase to the composition to avoid causing diarrhea in the horse which can lead to dehydration and possibly death. Therefore, in order to avoid diarrhea it is common sense to add lactase to the diet as such a concept is already established by Weese et al. Regarding the amount of lactase, liquid or powder dosage form and the size of the whey powder, the amount of a specific ingredient in a composition, the dosage form of the composition and the size of particular ingredient are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize or can judiciously select. Optimization of parameters is a routine practice that would be obvious for a person of

ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The expected and predictable result is reducing the energy deficit of the horse.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the nutrient component, feed component, amino acid chelate, trace mineral, monosaccharides, amino acids, liquid vitamin and functional food component as instantly claimed to a human, dog, cow, pig, goat or sheep, as suggested by the textbook of Lewis (Equine Clinical Nutrition), Parsons and common sense, in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art directs one to add these components to treat sick horses. As taught by Lewis (Equine Clinical Nutrition), *all the amino acids* are contained in the protein supplements. The expected result remains decreasing the energy deficit in the horse. It is known by the references that such compositions decrease the energy deficit, hence provide energy and would be expected to work in any mammal capable of digesting the product. Furthermore, it is merely judicious selection of an amino acid chelate or liquid vitamin in the absence of evidence to the contrary. Applicant has not invented amino acid chelates. A vitamin dissolved in solution would be a liquid vitamin. The expected and predictable result is reducing the energy deficit of the horse.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary:

Equine clinical nutrition, feeding and care are well known in the art of equine care. Textbooks have been written for the artisan on the subject. Providing lactase to lactose intolerant equines is also known in the art of equine care. Therefore, supplementing an equine in need of supplementation due to digestive tract conditions, hepatic dysfunction and renal dysfunction to reduce the energy deficit in the equine with whey protein and lactase is obvious to the ordinary artisan in view of the cited references.

Response to Arguments:

Applicant asserts that Lewis, Lon (Feeding and Care of the Horse second edition; 1996, Blackwell Publishing Professional, Ames, Iowa) does not disclose a specialized diet comprising "a protein component comprising whey powder" or "between about 2% to about 2.5% fat". Applicant argues that common horse feed for healthy horses may contain 2%-6% fat does not render obvious a specific diet for a mammal with hepatic dysfunction, renal dysfunction, or digestive tract diseases. Applicant argues that the present invention teaches methods of providing

a special diet, which is different from normal diet, for a mammal that become energy deficient due to hepatic dysfunction, renal dysfunction, or digestive tract disease.

Respectfully, the "special diet" now only requires two components: a protein component (in any amount) comprising whey powder and about 2% to about 2.5% fat. The art already suggests feeding horses whey and fat which inherently provides energy to the equine thus reducing the energy deficit in the animal. How this "special diet" is any different from a "normal diet" is unclear and unsupported by objective evidence. In other words, the criticality of having the specific combination of any amount of whey powder and about 2% to about 2.5% fat in a diet for a mammal with hepatic dysfunction, renal dysfunction, or digestive tract diseases remains to be demonstrated.

Applicant asserts that Lewis teaches that protein intake for horses with kidney diseases must be limited and for horses with liver diseases a proper diet is in the form of a lower-protein grass forage. Applicant also points out that Lewis teaches away from feeding horses having a digestive tract condition with whey powder because whey powder is lactose enriched (*which the Examiner has already indicated in the rejection above*) and lactose can cause diarrhea. The Examiner has already pointed out that it is known in the art to add lactase for lactose intolerant animals to avoid such adverse outcomes as diarrhea. Indeed, the instant independent claims are not limited to what may be added and dependent claims 38, 52 and 53 contain lactase.

Applicant argues that Parsons also fails to teach the instant methods and teaches a low protein diet for horses having liver diseases and that the horses should avoid high-protein feeds and should be fed late cut hay (which is generally lower in protein). This argument is irrelevant because the instant claims are drawn to *any amount* of protein which includes low protein and

high protein compositions for use in the method. In other words, there is no limitation on the amount of protein to be used in the method. Consequently, any amount of protein reads on the instant invention. In fact, even claims 52 and 53 require a protein component comprising whey powder and lactase with between about 95% and less than 100% by weight whey powder. That describes the protein component in the composition but the protein component can still be any amount in the composition. In other words, for example, the composition could contain 1% protein component and the protein component comprises whey powder and lactase with between about 95% and less than 100% by weight whey powder. Or, for example, the composition could contain 98% protein component and the protein component comprises whey powder and lactase with between about 95% and less than 100% by weight whey powder. Thus, the instant claims are drawn to any amount of protein to be used in the method.

Applicant asserts that Weese teaches administration of lactase to treat lactose intolerant foals but that Lewis teaches that young horses have no lactose intolerance problems to be treated. This is a spurious argument as clearly the art of Weese teaches otherwise. If Applicant actually read the Abstract then Applicant would be aware that the foal had persistent diarrhea caused by Clostridum difficile.

The fact of the matter remains that Applicant has not demonstrated anything unexpected or surprising about administration of the two component "special diet" instantly claimed. It remains the Examiner's position that the instantly claimed method is nothing more than feeding a sick mammal a composition of whey protein that is low in fat. In view of the art of record, it requires no inventive skill to feed a sick mammal, such as a horse, whey protein that is low in fat. In view of the art of record, it requires no inventive skill to feed a sick mammal, such as a horse,

whey protein and lactase to avoid intestinal distress in horse while supplying a protein source because it is known that older horses do not have the enzyme to metabolize the lactose in whey. Thus it becomes merely judicious selection of known ingredients to feed the mammal to provide energy in the absence of evidence to the contrary. Applicant has not supplied that evidence.

Respectfully, these arguments are not persuasive, no unexpected results have been shown and synergy has not been argued. The claims remain rejected for at least these reasons and the reasons of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613